Remarks

Claims 1-25 are pending in the subject application. By this amendment, the applicants have amended claims 1, 2, 10-12, 14, and 20, have canceled claims 7, 9, 13, 15-19, and 21-25, and have added new claims 26-29. No new subject matter has been added by this amendment. Support for the amendments to the claims can be found in the subject application including, at pages 1, 5, 8, 7, 10 and Figure 1. Accordingly, claims 1-6, 8, 10-12, 14, 20, and 26-29 are now before the Examiner for consideration.

The amendments set forth herein should not be interpreted to indicate that the applicants have agreed with, or acquiesced to, the rejections set forth in the outstanding Office Action. Favorable consideration of the claims now presented, in view of the remarks and amendment set forth herein, is earnestly solicited.

As an initial matter, the applicants have amended the subject specification to have the "Cross-Reference to Related Application" section inserted as the first sentence(s) of the specification.

Claims 1-25 have been provisionally rejected on the ground of nonstatutory obviousness-type double-patenting as being unpatentable over claims 6, 8, 9, 13-16, 21-23, and 25 of copending Application No. 10/731,528, now U.S. Patent No. 7,186,707. The applicants respectfully traverse the grounds for this rejection. As noted in the Office Action, "the conflicting claims are not identical....[and] the copending Application is limited to treating ophthalmic disorders." The applicants respectfully submit that the subject application is directed to the use of steroidal quinols for estrogen replacement therapy. U.S. Patent No. 7,186,707 does not teach or suggest the applicants' claimed invention. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Claims 2-6 and 9, 18 and 19, and 24 and 25 have been provisionally objected to under 37 C.F.R. §1.75 as being substantial duplicates of claims 1, 14, and 20, respectively. The applicants respectfully submit that claims 2-6 and 9, 18 and 19, and 24 and 25 are not substantial duplicates of claims 1, 14, and 20. However, as noted above, the objection of claims 2-6, 9, 18, 19, 24, and 25 is moot in view of the amendments or cancellation of these claims. Accordingly, reconsideration and withdrawal of this objection under 37 CFR 1.75 is respectfully requested.

Claims 1-6 and 8-12 have been rejected under 35 U.S.C. §112, first paragraph as failing to comply with the enablement requirement. The applicants respectfully traverse this grounds for rejection because a person skilled in this art could readily practice the full scope of the invention without undue experimentation. It is well established in the Patent Law that the mere breadth of a claim does not necessarily render the claim unpatentable for lack of enablement. In the current case, the applicant respectfully submits that chemists, biochemists, and pharmaceutical chemists, for whom this invention is intended, are highly skilled and could readily, and without undue experimentation, practice the claimed invention. This is all that is required to satisfy the enablement requirement.

As noted above, the applicants have canceled claim 9, thereby rendering moot the rejection of this claim. In addition, claims 10-12 have been amended to remove any reference to the preventative treatment of conditions. Claim 1 (from which claims 2-6, 8, and 10-12 depend) has now been amended to include the quinol of claim 13 (now canceled). Since claim 13 was not included in this rejection, it is respectfully submitted that the rejection of any of the currently presented claims is now rendered moot. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §112, first paragraph, is respectfully requested.

Claims 1-6, 8-12, 18, 19, 24, and 25 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. In order to expedite prosecution, claim 2 has been amended to include an identifying structure that correlates to the quinol (of claim 13) presented in claim 1. Claims 10-12 have been amended to clarify the specific conditions associated with menopause, bone or heart disease that can be treated using the steroidal quinols as provided in the specification. Claims 9, 18, 19, 24, and 25 have been canceled, thus rendering the rejection of those claims moot. In addition, as noted above, claim 1 has been amended to incorporate the limitations of claim 13, which was not included in this rejection, thus rendering moot the rejection of claims 1-6 and 8-12. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §112, second paragraph is respectfully requested.

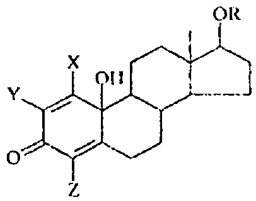
Claims 1-9 have been rejected under 35 U.S.C. §102(b) as being anticipated by Jiu #1 (U.S. Patent No. 2,910,486). The applicants respectfully traverse this grounds of rejection because the Jiu

#1 reference does not teach or even suggest the currently claimed process of using steroidal quinols for estrogen replacement therapy.

Claim 7 has been canceled, thereby rendering moot the rejection of this claim. In addition, the applicants have now amended claim 1 (from which claims 2-6, 8, and 10-12 depend) to include the limitations of claim 13 (now canceled). Since claim 13 was not included in the anticipation rejection, it is respectfully submitted that this rejection is now rendered moot. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

Claims 14, 15, and 17-25 have been rejected under 35 U.S.C. §102(b) as being anticipated by Numazawa *et al.* The applicants respectfully traverse this grounds of rejection because the Numazawa *et al.* reference fails to teach or even suggest the currently claimed quinols and pharmaceutical compositions derived thereof.

As an initial matter, claims 15, 17-19, and 21-25 have been canceled, thereby rendering moot the rejection of those claims. Claims 14 and 20 have been amended herein to describe quinols having the following structure:



wherein X, Y, and Z are hydrogen and R is alkyl. Numazawa *et al.* describe various 19-nor steroids and intermediate compounds used to produce the new steroids. None of the compounds disclosed by Numazawa *et al.* include those recited in claims 14 and 20.

It is basic premise of patent law that, in order to anticipate, a single prior art reference must disclose within its four corners, each and every element of the claimed invention. In *Lindemann v. American Hoist and Derrick Co.*, 221 USPQ 481 (Fed. Cir. 1984), the court stated:

> Anticipation requires the presence in a single prior art reference, disclosure of each and every element of the claimed invention, arranged as in the claim. *Connell v. Sears Roebuck and Co.*, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983); *SSIH Equip. S.A. v. USITC*, 718 F.2d 365, 216 USPQ 678 (Fed. Cir. 1983). In deciding the

> issue of anticipation, the [examiner] must identify the elements of the claims, determine their meaning in light of the specification and prosecution history, and identify corresponding elements disclosed in the allegedly anticipating reference. *SSIH, supra; Kalman [v. Kimberly-Clarke*, 713 F.2d 760, 218 USPQ 781 (Fed. Cir. 1983)] (emphasis added). 221 USPQ at 485.

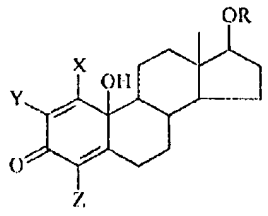
In *Dewey v. Almy Chem. Co. v. Mimex Co.*, Judge Learned Hand wrote:

> No doctrine of the patent law is better established than that a prior patent . . . to be an anticipation must bear within its four corners adequate directions for the practice [of the subsequent invention] . . . if the earlier disclosure offers no more than a starting point . . . if it does not inform the art without more how to practice the new invention, it has not correspondingly enriched the store of common knowledge, and it is not an anticipation. 124 F.2d 986, 990; 52 USPQ 138 (2nd Cir. 1942).

As noted above, the Numazawa *et al.* reference does not disclose the quinols now presented in claims 14 and 20. Thus, under the applicable statutory and case law, the Numazawa *et al.* reference does not anticipate the current claims. Therefore, reconsideration and withdrawal of the rejection under 35 USC §102(b) is respectfully requested.

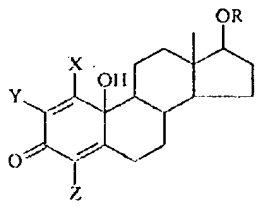
Claims 14, 20, and 23-25 have been rejected under 35 U.S.C. §102(b) as being anticipated by Ohe *et al.* The applicants respectfully traverse this grounds of rejection because the Ohe *et al.* reference fails to teach or even suggest the currently claimed quinols and pharmaceutical compositions derived thereof.

As an initial matter, claims 23-25 have been canceled, thereby rendering moot the rejection of those claims. In addition, claims 14 and 20 have been amended herein to describe quinols having the following structure:



wherein X, Y, and Z are hydrogen and R is alkyl. As indicated in the Office Action, Ohe *et al.* only teaches 10β,17β-dihydroxy-1,4-estradiene-3-one and ethyl acetate solution thereof. As discussed above, for a proper rejection under 35 USC §102, a single prior art reference must, within its four corners, disclose each and every element of the claimed invention. Ohe *et al.* fail to describe or suggest the steroidal quinols recited in claims 14 and 20. Accordingly, reconsideration and withdrawal of the rejections under 35 USC §102 is respectfully requested.

Claims 14 and 17-19 are rejected under 35 U.S.C. §102(b) as being anticipated by Jiu #2 (U.S. Patent No. 2,950,291). The applicants respectfully traverse this grounds of rejection because the Jiu#2 reference fails to teach or even suggest the currently claimed quinols and pharmaceutical compositions derived thereof. As noted above, claims 17-19 have been canceled and claim 14 has been amended herein to recite a quinol having the following formula:



wherein X, Y, and Z are hydrogen and R is alkyl. The currently claimed quinols are not disclosed or suggested by Jiu#2. Accordingly, reconsideration and withdrawal of the rejections under 35 U.S.C. §102 is respectfully requested.

The applicants have also added new claims 26-27, which include the quinol set forth in claim 13. Also added are new claims 28-29, which include a quinol as set forth in original claims 14 and 20. Since the cited references do not teach the quinols recited in new claims 26-29, it is respectfully submitted that new claims 26-29 are also not anticipated by Jiu#1, Numazawa *et al.*, Ohe *et al.*, or Jiu #2.

Claims 1-12 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Jiu#1. The applicants respectfully traverse this rejection because the Jiu#1 reference fails to teach the use of their steroidal quinol in estrogen replacement therapy.

As noted above, claim 7 has been canceled and claim 1 (from which claims 2-6, 8, and 10-12 depend) has been amended to include the limitations of claim 13 (now canceled). Since claim 13 was not included in this rejection, it is respectfully submitted that the rejection of the claims under 35 U.S.C. §103 are now rendered moot. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

In view of the foregoing remarks and amendments, the applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

The applicants also invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,

Margaret Efron
Patent Attorney
Registration No. 47,545
Phone: 352-375-8100
Fax No.: 352-372-5800
Address: P.O. Box 142950
Gainesville, Florida 32614-2950

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